REMARKS

Claims 54-85 are pending. Claims 1, 9, 10, 13-22, 26, 30, 34, 36, 40 and 44-53 are cancelled without prejudice to the prosecution of their subject matter in other applications. New claims 54-85 are added, and are supported by the specification as follows.

Claims 54 and 55, and 70 and 71, drawn to a nucleic acid encoding Progression Suppressed Gene-13 ("PSGen13") protein, are supported by the specification at page 6 lines 12-13, and Figures 1 and 2, respectively. Claims 54, 55, 70 and 71 drawn to a nucleic acid encoding PSGen13 linked to an enhancer element, are supported by the specification at page 21 lines 25-31. Claims 58-63 and 74-79, drawn to host cells prepared by contacting the cells with a nucleic acid encoding PSGen13 protein such that the cells express PSGen13 protein, are supported by the specification at page 7 lines 5-18. Claims 56, 57, 72 and 73, drawn to vectors containing nucleic acids encoding PSGen13 protein, are supported by the specification at page 6 lines 30-31 and page 15 line 13 through page 20 line 35. Claims 64-69 and 80-85, drawn to host cells containing the vector, are supported by the specification at page 6 line 31 through page 7 line 3. None of these new claims contain new matter, and it is believed that no additional claim fees are due.

The previously pending claims are rejected under 35 U.S.C. §112 and §102. For reasons to be set forth herein, the new claims have removed the bases for the rejections.

1. **The New Claims Are Clear And Definite**

Claims 9, 10, 30, 46, 48 and 50 are rejected under 35 U.S.C. §112 as indefinite for referring to "the polynucleotide sequence shown in SEQ ID NO:2," because SEQ ID NO:2 is a protein sequence.

The new claims properly refer to the nucleic acids encoding rat and human PSGen13 depicted in Figures 1 and 2 respectively, as SEQ ID NO:1 and SEQ ID NO:3 and refer to their encoded proteins as SEQ ID NO:2 and SEQ ID NO:4. Accordingly, the rejection should be withdrawn.

2. **The Claims Are Supported By The Specification**

First, claims 51 and 52 are rejected under 35 U.S.C. §112 as containing subject matter that was not adequately described in the specification, and in particular for reciting a list of tumor cells that can serve as host cells for the nucleic acids of the invention. The Examiner requests Applicants to point to support in the specification for the list of tumor cells.

The lists of tumor host cells provided in the new claims may be found in the specification at page 6 line 33 through page 7 line 3 and at page 7 lines 11-18. These lists support the lists found in the claims, so that the rejection should be withdrawn.

Second, claim 53 is rejected under 35 U.S.C. 112 as unenabled. The Examiner contends that since claim 53 is drawn to a *pharmaceutical* composition comprising a nucleic acid encoding PSGEN13, it impliedly is for *in vivo* use. According to the Examiner, the *in vitro* data provided in the specification are not sufficient to

support use of the claimed composition in treating cancer in view of a low level of predictability in the art.

Claim 53 is cancelled without prejudice, thereby rendering the basis for the rejection moot.

3. **The Claims Are Not Anticipated**

First, claims 1, 30, 44, 46, 48 and 53 are rejected under 35 U.S.C. §102(b) as anticipated by GenBank accession number AA 891725 (January 8, 1999).

Second, claims 1, 9, 10, 30, 44 and 53 are rejected under 35 U.S.C. §102(a) as anticipated by Fisher (WO 99/43844, 02-Sept-1999; "Fisher") which teaches an isolated nucleic acid PSGen13 at Figure 35B and claim 21, and a vector and host cell at page 47.

None of the new claims are anticipated by the cited art. The new claims each provide for a PSGen-13 encoding sequence operably linked to an enhancer element, subject matter which is not disclosed in GenBank sequence AA891725 or Fisher.

GenBank Acc. # AA891725 provides the sequence for an expressed sequence tag ("EST") derived from rat kidney. The *reverse complement* of the complete, correct coding sequence for rat PSGEN-13 is found within the EST, and no function is provided. There is no teaching of operably linking an enhancer element to the EST, nor is any motivation to do so provided.

The PSGen13 sequence provided by Fisher does not encode the protein sequence of SEQ ID NO:2. There are approximately 4 nucleotide errors in the rat PSGen13 sequence provided in Fisher which result in a shift in the translational reading

frame, so that the rat PSGen13 protein disclosed in Fisher differs from that of the present invention by approximately 50%.

Neither of these citations enables the presently claimed invention. Neither discloses the correct sequence of rat PSGen13 nucleic acid or protein. Neither discloses a nucleic acid encoding a PSGen13 protein (human or rat) operably linked to an enhancer element (nor, necessarily, such nucleic acids incorporated into a vector or host cell). Therefore, these citations cannot anticipate the claims, and Applicants request that the rejections be withdrawn and not be applied to the new claims.

Applicants would also like to invite the Examiner's attention to the following publicly released sequences:

(1) GenBank Acc. # H34607, a rat EST containing slightly more than half of the rat PSGen13 coding sequence, which we were informed was publicly available July 19, 1995;

(2) GenBank Acc. # AI44570, a portion of the rat PSGEN13 sequence outside of the coding region dated November 23, 1998;

(3) GenBank Acc# AW024795, a reverse complement of, *inter alia*, the human PSGen13 coding sequence, which we were informed was publicly available September 13, 1999;

(4) GenBank Acc. # AF161398, containing the complete human PSGen13 nucleic acid and its encoded protein, publicly released February 1, 2000 (submitted May 14, 1999); and

(5) GenBank Acc. # AF116682, containing the complete human PSGen13 nucleic acid and its encoded protein, publicly released May 21, 2000 (submitted December 24, 1998).

Copies of the GenBank listings are provided as part of the Information Disclosure Statement and PTO 1449 form provided herewith, where these sequences are listed as items 18, 11, 15, 10 and 14, respectively.

In addition to the reasons presented above as to why neither GenBank Acc. # AA891725 nor Fisher anticipate the claimed invention, Applicants assert that none of GenBank Acc.#s H34607, AI144570, AW024795, AF161398, or AF 116682 would anticipate the claimed invention. None of these sequences contain a PSGen13-encoding nucleic acid linked to an enhancer element such that PSGen13 protein would be in expressible form.

Moreover, neither the cited art nor the above-listed sequences would render the claimed subject matter obvious. GenBank Acc. #s AA891725 and AW024795 are reverse complements of the actual coding sequence, and do not define a specific protein. GenBank Acc. # H34607 is a partial coding sequence, and GenBank Acc. # AI144570 is outside the coding region. . Neither GenBank Acc. #s AA891725, H34607, AW024795, AF161398, nor AF 116682 provide any function for the recited sequences, much less suggest a role for the actual PSGen13 protein in reversing malignant characteristics in cells.

Fisher teaches an incorrect sequence for rat PSGen13 nucleic acid and protein. This would not be readily appreciated from the publicly available rat sequences, which could be allelic variants or pseudogenes. The partial sequence GenBank Acc. #H34607 and the reverse complement AA891725 provide no functional information that would lead the skilled artisan to suspect that the sequence set forth in Figure 35B of Fisher was wrong. GenBank Acc. #AI144570 is irrelevant to the protein coding sequence.

Fisher does not disclose or suggest the human PSGen13 nucleic acid or protein sequence.

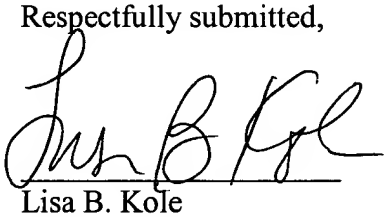
Therefore, Applicants assert that none of these sequences or citations would anticipate or render obvious the new claims.

Accordingly, it is requested that the rejection be withdrawn.

4. Conclusion

For all the foregoing reasons, Applicants request that the new claims be deemed allowable.

Respectfully submitted,



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